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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/606,709 | 06/26/2003 | John R. Squilla | 85296DMW | 5065 |

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| EXAMINER | |
|---|---|
| BITAR, NANCY | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 2624 | |

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/606,709 | SQUILLA ET AL. | |
| | Examiner | Art Unit | |
| | Nancy Bitar | 2631 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 June 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *06/26/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 5 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

*As to claims 5, the phrases "such that" render the claims indefinite because it is unclear whether the limitations following the phrases are part of the claimed invention. See MPEP § 2173.05(d).*

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 1-8 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,512,994 to Sachdeva.

As to independent claim 1, Sachdeva et al discloses, a method for determining dental alignment of a 3-dimensional model of one or more teeth of a patient ( a method for producing a three-dimensional digital model of an orthodontic patient; column 3, lines 47-48), said method comprising the steps of:

(a) obtaining a radiograph (obtaining data of an orthodontic structure, column 3 lines 50-51, note that the data may be video data, x-rays, CAT scans, ultrasound, and/or magnetic resonance images, column 3 lines 57-59) of the teeth of the patient;

(b) obtaining a digital image from the radiograph indicative of the dental alignment of the teeth relative to a dental arch of the patient ( the orthodontic data may be obtained by scanning a patient mouth to obtain video data, column 4, lines 18-19) , Sachdeva et al teaches,

(c) overlaying the 3-dimensiional model of the teeth with the digital image obtained from the radiograph (map the two dimensional image of a tooth on the three dimensional model, multiple angles of the tooth should be used, column 5, lines 50-52); and

(d) determining vertical and horizontal mis-alignment of the teeth in the 3-dimensional model (determine the scaling factor, column 4,line 46)relative to the digital image obtained from the radiograph (scaling factor 28 determination is based on an assumption that the video data 10 will have a linear error, column 4, lines 57-58); and

(e) adjusting the 3-dimensional model to correct for the mis-alignment, thereby producing an adjusted 3-dimensional model of the teeth that is corrected for the vertical

and horizontal alignment of the teeth relative to the dental arch (the scaled digital model 48 of the tooth is positioned to be planer with the x-ray tooth 46.Having obtained the proper orientation between the two objects, the per tooth scaling factor is determined and subsequently used to generate the composite digital model 50 of the tooth(i.e. adjusted model), column 5,lines 40-45,figure 5).

As to dependent claim 2, Sachdeva et al teaches the method as claimed in claim 1 wherein the adjusted 3-dimensional model is used to fabricate prosthesis (i.e. crown 44). Note that making a patient's dental prosthesis can be considered a prosthesis tooth, crown, veneer, or bridge.

As to dependent claim 3, Sachdeva et al teaches the method as claimed in claim 1 wherein the step (e) of adjusting the 3-dimensional model comprises adjusting size (orthodontic data to match the actual orthodontic size, column 4 lines 31-32, figure 2), shape and position of the teeth in the 3-dimensional model (FIGS. 7 and 8. Note that an external positioning system may be used to obtain the orientation reference points).

As to dependent claim 4, Sachdeva et al teaches the method as claimed in claim 1 wherein the step (b) of obtaining the digital image comprises identifying key vertices of the teeth in the radiograph and fitting a vertices curve through the vertices (determine the scaling factor. For example, the differences in area formed by the triangles may be used to generate the scaling factor, the coordinate differences between each of the vertices of the triangle may be utilized, column 4,lines 46-49).

As to dependent claim 5, Sachdeva et al teaches the method as claimed in claim 4 wherein the step (c) of overlaying comprises overlaying the vertices curve over the 3-

dimensional image such that the curve is used in step (d) to determine mis-alignment (the orientation reference points 62 and 66 will be subsequently used to map the digital image of the orthodontic structure, column 5, lines 50-61, note that in figure 8 the rotation 82 with respect to the x-y plane determines the mis-alignment). Moreover Sachdeva teaches the misalignment of the common features of the 3D model relative to the image of the object by projection (i.e. overlaying) the model onto an image of the image of the object and applying a 3D morphing algorithm to correct for the misalignment (Fig 9,element 100 and Fig 8,element 82).

As to dependent claim 6, Sachdeva et al teaches the method as claimed in claim 1 wherein the step (b) of obtaining the digital image comprises identifying the center of mass points of the teeth in the radiograph and fitting a center of mass curve through the center of mass points (i.e. mid-point frenum, incisive papilla, rugae, cupid's bow, inter-pupillar midpoint, inter-commissural midpoint, inter-alar midpoint, prone nasale, sub-nasale, dental mid-line point, a fixed point on a bone, a fixed bone marker such as implants that resulted from a root canal, oral surgery, etc.( column 8, lines 14-25).Thus, the center of mass point can be any of these reference point.

As to dependent claim 7, Sachdeva et al teaches the method as claimed in claim 6 wherein the step (c) of overlaying comprises overlaying the center of mass curve over the 3-dimensional image such that the center of mass curve is used in step (d) (scaled data id mapped to a coordinate system based on at least two reference points, column 8, lines 26-27) to determine mis-alignment (integrated simulation model to determine alignment, column 8, lines 36-37).

As to dependent claim 8, Sachdeva et al teaches the method as claimed in claim 1 wherein the step (a) of obtaining the digital image comprises forming an outline of one or more teeth in the radiograph, and wherein the outline is used in step (d) to determine mis-alignment (i.e. edges, cusps etc....column 8, line 12; note that the crown is roughly triangular in outline; the incisor edge is nearly a straight line, though slightly crescent shaped).

As to dependent claim 10, Sachdeva et al teaches the method as claimed in claim 9 wherein the horizontally aligned vertical reference is located relative to the highest point on the teeth and to the position of the gum line (the data is scaled based on the at least one scaling reference i.e. horizontal aligned vertical reference where surface data which may be obtained as video data is scaled first, column 7, lines 47-51, note that video data includes information regarding the teeth surface, gum surface, lips surface and facial surface, column 7, lines 35-36).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva in view of Rubbert et al. (U.S. Patent No. 4,648,640).

7. As to dependent claim 9, note the discussion of Sachdeva above, Sachdeva et al. disclose the method for producing a three-dimensional digital model of an orthodontic patient; (column 3, lines 47-48) by determining a scaling factor for the orthodontic data. As shown, an actual tooth 32 is marked with a marking 34. The marking 34 is of a substantial size to be adequately measured (column 4, lines 64-67). Sachdeva does not teach the use of displacement to create a template or fixture. Rubbert et al. clearly teaches the step of measuring the displacement of one or more key points on each tooth in the digital image from a horizontally aligned vertical reference (single set of points defining the boundaries of the tooth, column 50, lines 42-43), and using the displacement to form a template or fixture (template tooth, figures 58A-58F) that can be used to check the fit of the prosthesis fabricated from the adjusted 3-dimensional model relative to a gum line (the proper axial rotation of the template tooth to have it fit properly with respect to the tooth column 50, lines 46-48). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the template tooth as taught by Rubbert et al to the scaling factor of Sachdeva to make sure that the algorithm works even if there are significant differences between the original template tooth and scanned point cloud (column 51, lines 5-8).

As to dependent claim 11, Sachdeva et al teaches the varying amount of distortion from tooth to tooth depending on the distance of the tooth from the film, the angle of x-ray transmission etc. and he also explained that to get more accuracy one has to map the two dimensional tooth images on to the three dimensional model, multiple angle of the tooth should be used (column 5, lines 48-52). But Sachdeva does

not teach that the distance of the teeth is independent from the gum line. Rubbert et al. clearly teaches the horizontally alignment vertical reference in an arbitrary distance from the teeth independent of the gum line (the calibration relationship of the scanner that gets distance information in X and Y directions, for the numerous portions of the pattern, column 9, lines 6-8) note that the teeth are separated from each other and from the gums, they can be individually manipulated, column 6,lines 48-49). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use these calibration relationships as taught by Rubbert et al to the distance of the tooth from the film of Sachdeva that could be equivalently represented by one or more mathematical functions as will be apparent to those skilled in the art (column 9, lines 11-13).

***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Feldman et al. (US 2005/0084144 A1) is cited to teach the production of an artifact corrected image using a digital image in a recipient jaw.

Snyder et al. (US 6,195,474) is cited to teach digitizing dental radiographs to assist in dental alignment.

Rubbert et al. (US 6,648,640) is cited to teach a computerized, interactive method for orthodontic treatment using 3D information of an object.

Phan et al. (WO 01/80763 A2) is cited to teach the integration of 3D data by generating a digital teeth model with the marker point ;and align the two or more 3D anatomical maps and the teeth model using the marker points.

***Inquiries***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Bitar whose telephone number is 571-270-1041. The examiner can normally be reached on Mon-Fri (7:30a.m. to 5:00pm).
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chanh Nguyen can be reached on 571-272-0000. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nancy Bitar

08/10/06

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SUPERVISORY PATENT EXAMINER